NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ADAPT PHARMA OPERATIONS LIMITED, *et al.*, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., *et al.*, Defendants.	Civil Action Nos.: 16-7721, 17-2877, 17-864, 17-5100, 18-9880 (JLL) **OPINION**

LINARES, Chief District Judge,

This matter comes before the Court by way of an application for claims construction by Plaintiffs Adapt Pharma Operations Limited, Adapt Pharma, Inc., and Opiant Pharmaceuticals, Inc. ("Adapt") and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. ("Teva"). Specifically, the parties seek construction of certain language contained in Claim 1 of United States Patent Numbers 9,211,253 ("'253 patent") and 9,468,747 ("'747 patent"), Claim 10 of the '253 patent and '747 patent, and Claim 29 of United States Patent No. 9,629,965 ("'965 patent").[1] The Court has considered the parties' written submissions, (ECF Nos. 65, 70, 160, 162), and the oral arguments advanced at the *Markman* hearing held on March 31, 2019. (ECF No. 188).

[1] The parties additionally sought the Court's construction of the terms "about 0.2 mg of a stabilizing agent / about 0.2 mg disodium edetate / about 0.2% (w/v) disodium edetate as the stabilizing agent" found in Claims 1 and 3 of the '253 patent, Claims 3 and 33 of the '747 patent, Claims 5 and 27 of United States Patent No. 9,561,177 ("'177 patent"), and Claims 1 and 22 of the '965 patent. They have since resolved their dispute regarding these terms. (ECF No. 194).

I. BACKGROUND

A. The Patents

The subject patents deal with, and relate to, the administration of a nasal spray form of an opioid receptor antagonist known as the drug "naloxone." ('253 patent at 1:8–12; 2:9–11).[2] Naloxone is used to reverse opioid overdoses and for "adjunct" use to treat septic shock. (*Id.* at 13–15). The FDA has previously approved naloxone treatments in the form of injection. (*Id.* at 9–11). There is debate about the relative effectiveness of the nasal delivery method of naloxone ingestion compared to various injection methods via IV, intramuscular injection, or subcutaneous administration. (*Id.* at 2:43–6:4).

Adapt asserts that the patents cover its brand name drug Narcan®, which is a nasal spray comprising 4mg of naloxone hydrochloride. (ECF No. 65 at 6, '253 patent at 9:34). Adapt received FDA approval for Narcan® on November 18, 2015 (NDA No. 208411, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208411). Narcan is the first and only FDA approved nasal spray to combat opioid overdose. (ECF No. 65 at 6). The patents-in-suit describe pre-primed "devices adapted for nasal delivery of a pharmaceutical composition to a patient, comprising a therapeutically effective amount of an opioid antagonist selected from naloxone and pharmaceutically acceptable salts," in amounts ranging from 2mg to 12mg of naloxone hydrochloride. ('253 patent at 6:54–60). The patents-in-suit also describe methods of treating an opioid overdose using this device, "comprising nasally

[2] A copy of the '253 patent can be found at ECF No. 65-2. The Court cites only to the '253 patent except for issues that refer specifically to one of the other patents-in-suit.

administering to a patient in need thereof" the aforementioned therapeutically effective naloxone hydrochloride dosage. (*Id.* at 6:61–67). Adapt markets Narcan® as a product that fills the need for a "durable, easy-to-use, needleless device[] with storage-stable formulations that can enable untrained individuals to quickly deliver a therapeutically effective dose of a rapid-acting opioid antagonist to an opioid overdose patient." ('253 patent at 6:43–47).

B. Disputed Term and Proposed Construction

The parties have asked the Court to construe the following terms:

Disputed Term	Patent Claims that the Term Appears In
"delivery time"	Claim 10 of the '253 patent, Claim 10 of the '747 patent, and Claim 29 of the '965 patent
"a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 μL"[3]	Claim 1 of the '253 patent and Claim 1 of the '747 patent

Adapt proposes that this Court construe the above terms in the following manner:

Disputed Term	Plaintiffs' Proposed Construction
"delivery time"	"the amount of time that elapses between a determination made by a healthcare professional, or an untrained individual that an individual is in need of nasal delivery of an opioid antagonist and completion of the delivery."
"a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 μL"	Requires no construction

(ECF No. 65 at 13, 15).

[3] μL stands for microliter, which is one millionth of a liter and is numerically represented as 1×10^{-6} m.

Teva proposes the following constructions for the disputed terms:

Disputed Term	Defendant's Proposed Construction
"delivery time"	Indefinite
"a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 μL"	"a single device reservoir filled with approximately 100 μL of an aqueous pharmaceutical composition."

(ECF No. 70 at 8, 21).

II. LEGAL STANDARD

A court's analysis of a patent infringement claim is two-fold. *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002). The court must first define the meaning and scope of the patent claims as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The court then engages in a comparison of the claims as construed to the alleged infringing product or method. *Tate*, 279 F.3d at 1365. At this stage, the Court must only engage in the first step.

Claim construction is a matter of law to be determined solely by the court. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Id.* at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). In construing the terms of a patent, a court should look first to the language of the claim itself. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The terms in the claim "are generally given their ordinary and customary meaning." *Id.* at 1582. "[T]he ordinary and customary meaning of a claim term is

the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313. A court "must look at the ordinary meaning in the context of the written description and the prosecution history." *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) (quoting *DeMarini Sports, Inc. v. Worth*, 239 F.3d 1314, 1324 (Fed. Cir. 2001)). The court should turn to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Innova/Pure*, 381 F.3d at 1116.

To this end, the court should first examine the intrinsic record—the patent itself, including the claims, the specification and, if in evidence, the prosecution history. *Vitronics*, 90 F.3d at 1582 (citing *Markman*, 52 F.3d at 979). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Id.* Indeed, the Federal Circuit has explained that the specification is "'usually . . . dispositive . . . [and] the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317. The specification is also an important guide in claims construction as it may contain "an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1316.

Additionally, the court should consult the patent's prosecution history as it "provides evidence of how the PTO and the inventor understood the patent." *Id.* at 1317. Courts should be circumspect in reviewing a prosecution history as it represents "an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation." *Id.* A district court may also examine extrinsic evidence: "all evidence external to the patent and prosecution history." *Markman*, 52 F.3d at 980; *see also Phillips*, 415 F.3d at 1317 (stating that the Federal Circuit

"ha[s] authorized district courts to rely on extrinsic evidence"). Such evidence consists of testimony by the inventor or by experts, dictionaries, and treatises. *Markman*, 52 F.3d at 980. In particular, a court may find reference to technical dictionaries useful "in determining the meaning of particular terminology." *See Phillips*, 415 F.3d at 1318. However, extrinsic evidence is generally thought to be less reliable than the patent and prosecution history, *id.* at 1318–19; in essence, it is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language,'" *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting *Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1318 (Fed. Cir. 2004)).

Finally, a party may challenge the definiteness of a disputed term. Should the Court find the term indefinite the claim is rendered invalid. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901–02 (2014). "A lack of definiteness renders invalid 'the patent or any claim in suit.'" *Nautilus*, 572 U.S. at 902 (quoting 35 U.S.C. § 282, ¶2(3)). The Federal Circuit recently confirmed that "[i]ndefiniteness must be proven by clear and convincing evidence." *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017). The "indefiniteness analysis involves general claim construction principles." *Sonix*, 844 F.3d at 1378.

III. ANALYSIS

A. Indefiniteness

Teva advances an indefiniteness challenge with respect to "delivery time." Teva asserts that "tying delivering time to a subjective 'determination made by a healthcare professional or an untrained individual,' . . . fail[s] to provide any reasonable certainty as to the scope of the claims. (ECF No. 70 at 21). Teva also argues that the purported end point of the "delivery time,"—

"completion of delivery"— is similarly ambiguous. (ECF No. 70 at 21). As to the determination made by a healthcare professional or untrained individual, Teva argues that such a determination is the "formation of a mental impression," and that the patent "provides no guidance whatsoever as to how to determine when such an event has occurred," nor could it, as the thought process occurs in the observing individual's head. (ECF No. 70 at 21–22). For example, Teva argued at the *Markman* hearing that "there is no definition in the specification of what the determination is. You can imagine that the determination could be a period of evaluation. You could imagine that while they are evaluating, they are preparing the device to deliver." (ECF No. 193 ("Tr.") at 10:16–20). This ambiguity is exacerbated, Teva argues, by the difference between a medical professional's ability to determine the symptoms of an overdose as opposed to a layperson's. (ECF No. 70 at 22). Regarding the "completion of delivery," Teva argues that is unclear "whether delivery is complete when the nasal spray leaves the medical device, when the spray reaches the nasal mucosa, when the naloxone enters the blood stream, or when the naloxone is actually delivered to the opioid receptors." (ECF No. 70 at 22).

Adapt contends that the inventors of the device "acted as their own lexicographers and expressly defined 'delivery time' . . . [and that] Teva cannot point to anything in the inventors' easily-understood definition of 'delivery time' that would make it difficult for a [person of ordinary skill in the art] to discern with reasonable certainty what is meant by that term."[4] (ECF No. 65 at 13–14). Adapt believes that the process of making the determination to administer the naloxone is not part of the "delivery time" and that "the people administering the drug—whether trained or

[4] The parties have not come to an agreement on who a person of ordinary skill in the art might be in this context, nor has either party proposed their own definition for a person of ordinary skill in the art.

untrained—know when they set out to administer the drug, and anyone else trying to 'measure' 'delivery time' from that starting point could simply ask them, or tell them to start a stopwatch, or to look at the clock and later report the time." (ECF No. 162 at 11). In other words, "the determination, however long it may take to make that determination, is made prior to the delivery time commencing." (Tr. at 21:23–25). Adapt also argues that the "completion of the delivery" is clear, in that a person of ordinary skill in the art would understand that term to mean the completion of nasal deliver, *i.e.*, "when the pharmaceutical composition has been sprayed into the nose." (ECF No. 162 at 11).

Adapt also urges this Court to consider Teva's indefiniteness argument at trial, arguing that it would be premature at the claims construction stage. (ECF No. 65 at 8). This Court agrees. It is not uncommon for courts to defer ruling on an indefiniteness challenge at the claims construction stage where such a ruling would be better suited for trial. *See Alcon Research, Ltd. v. Barr Labs. Inc.*, No. 09-0318, 2011 WL 3901878, at *16 (D. Del. Sept. 6, 2011) (collecting cases). There are a number of factors present here that push the Court to defer a ruling on indefiniteness. First, the parties do not agree on, nor have they proposed, any qualifications or characteristics of a person of ordinary skill in the art. *See Research Frontiers, Inc. v. E Ink Corp.*, No. 13-1231, 2016 WL 1169580, at *20 (D. Del. Mar. 24, 2016) (declining to take up E Ink's indefiniteness challenge where the parties "clearly disagree[d] as to what qualifications a person skilled in the relevant art would have, . . . [a]nd there [was] scant information in the record about what *is* the relevant level of skill in the art"). Additionally, the Court has not heard expert testimony or read expert reports concerning the distribution and administration of Narcan® nasal spray to those in need, as expert discovery is still ongoing. *See Purdue Pharm. Prods., L.P. v. Actavis Elizabeth, LLC*, No. 12-

5311, 2014 WL 2624787, at *6 (D.N.J. June 11, 2014), *aff'd* 627 F. App'x 931 (Fed. Cir. 2016) (concluding that a finding of indefiniteness would be premature in part due to the lack of expert testimony in the record); *see also McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1362 (Fed. Cir. 2001) ("Mere attorney argument is no substitute for evidence of record"); *WesternGeco L.L.C. v. ION Geophysical Corp.*, 876 F. Supp. 2d 857, 875 (S.D. Tex. 2012) ("Defendants' unsupported attorney argument fails to prove indefiniteness by clear and convincing evidence."); *Cacace v. Meyer Mktg. (Macau Commercial Offshore) Co.*, 812 F. Supp. 2d 547, 561 (S.D.N.Y. 2011) (finding attorney argument in support of indefiniteness insufficient to establish invalidity).

Moreover, where, as here, the indefiniteness challenge has to do with a method of measurement—in this case, the measurement of time between the determination that someone needs Narcan® and the completion of that delivery—there must be "clear and convincing evidence that the method of measurement is in fact outcome-determinative in the infringement analysis." *Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359, 1367 n.4 (Fed. Cir. 2014). And inconsistent results from a method of measurement alone would not necessarily render a claim indefinite. *Id.* at 1367 n.3. Thus, because the indefiniteness argument in this claim construction is "potentially dispositive, require[s] a high burden of proof, and may more profitably be considered in connection with patent validity," the Court declines to rule on the indefiniteness of "delivery time" at the claims construction stage. *Fresenius Kabi USA, LLC v. Fera Pharm., LLC*, No. 15-3654, 2016 WL 5109142, at *9 (D.N.J. Sept. 20, 2016).

B. Claim Construction

The Court now turns its attention to the remaining disputed term.

a. "a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 μL"

The term "a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 μL" appears in Claim 1 of the '253 and '747 patents. ('253 patent at 21:8–9, 50:39–40; '747 patent[5] at 22:12–13, 53:13–15).

Teva construes the term to mean "a single device reservoir filled with approximately 100 μL of an aqueous pharmaceutical composition." (ECF No. 70 at 8). Teva's issue with the term is that in Adapt's infringement contentions, "Adapt treats the 100 μL as if it referred to the amount of the pharmaceutical composition delivered to the patient rather than the amount present in the reservoir of the device," when the "text of the claim makes clear that the 100 μL is the amount in the device reservoir." (ECF No. 70 at 9). Teva points to the dependent claims of the '253 and '747 patents, as well as the specifications of those patents, as support for its proposed construction. It argues that because Claim 6 of the '253 patent, which depends from Claim 1, "specifies that 'about 100 μL of said aqueous solution in said reservoir is delivered to said patient in one actuation,'" Adapt "knew how to draft claims regarding the amount of drug administered to a patient when it wanted to do so." (ECF No. 70 at 10). Teva also points to the '253 patent specification language, which tracks the language of Claim 1, as evidence that the claim covers a reservoir limited to containing 100 μL of the drug. (ECF No. 70 at 10).

Adapt proposes that this term requires no construction and that the plain and ordinary meaning of the claim language controls. (ECF No. 65 at 15). Adapt believes that Teva's proposed constructions reads improper limitations into the claim in three ways. First, Teva unnecessarily

[5] The '747 patent can be found at ECF No. 65-3.

adds the limitation of "device" to a "a single device reservoir." (ECF No. 65 at 16). Second, Adapt contends that replacing "comprising" with "filled with" replaces a "broad, open-ended term of art that means that an embodiment of the claims must contain certain elements but can also include other things," with a "narrow, closed-ended term that would unduly limit the scope of the claims." (ECF No. 65 at 16). Third, Adapt argues that replacing "about" with "approximately" is an exercise in redundancy. (ECF No. 65 at 16–17).

Teva has abandoned two of its challenged changes. As to whether the claim reads "a single reservoir" or "a single device reservoir," the parties agree that the reservoir is part of the device. (Tr. at 58:24–25). Teva's counsel Mr. Rozendaal also admitted that he does not "think it matters whether we call it a device reservoir or just a reservoir." (Tr. at 59:2–3). Teva has also conceded that "approximately" and "about" are synonymous. (ECF No. 160 at 12). Thus, the Court sees no need to unnecessarily address these revisions and will leave these claims terms as Adapt has written them. *See K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999) ("Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.").

The remaining dispute centers around the volume of the pharmaceutical composition in the reservoir and the makeup of the solution in the reservoir. Adapt suggests that the word comprising's plain and ordinary meaning governs. "Comprising" is an "open-ended term . . . of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997). Teva suggests replacing "comprising" with "filled," a term that is defined in the '253 patent. The patent defines that term as follows: "[t]he term 'filled,' as used herein, refers to an association between a device and a pharmaceutical composition, for

example, when a pharmaceutical composition described herein comprising a therapeutically effective amount of an opioid antagonist is present within a reservoir that forms a part of a device described herein." ('253 patent at 9:15–21). Adapt, however, chose not to use this word in the claim at issue and instead used the word "comprising." This deliberate word choice should not be ignored. *See Tex. Dig. Sys., Inc., v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002) ("The terms used in the claims bear a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art.").

The dependent claims in the patent lend support to the use of "comprising" over "filled." Most persuasively, Claim 5 of both the '253 and '747 patents reads: "wherein the volume of said reservoir is not more than about 140 μL." ('253 patent at 50:63–64; '747 patent at 53:40–41). Claim 5 thus imposes an upper limit on the volume of the reservoir in the device. Given that the Court "must not interpret an independent claim in a way that is inconsistent with a claim that depends from it," construing the claim as having an upper limit of 100 μL would violate one of the maxims of claim construction. *Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1445 (Fed. Cir. 1997).

Additionally, Claim 6 of the '253 and '747 patents states that "wherein about 100 μL of said aqueous solution in said reservoir is delivered to said patient in one actuation." ('253 patent at 50:65–67; '747 patent at 53:42–44). Elsewhere, the '253 patent specification also informs us that "[t]o emit 100 μL, a volume of 125 μL is filled in the device." ('253 patent at 16:51–52). Thus, Teva's argument that the "text of the claim makes clear that the 100 μL is the amount in the device reservoir," (ECF No. 70 at 9), is simply inconsistent with the dependent claims in the '253 and '747 patents. It is evident from reading Claim 6 in conjunction with the patent specification

that the device is designed to deliver 100 μL of the aqueous pharmaceutical composition to the patient, and that in order to do so, the reservoir must be filled with a volume greater than 100 μL. *See Trs. of Columbia Univ. in the City of N.Y. v. Symantec Corp.*, 811 F.3d 1359, 1362, 1370 (Fed. Cir. 2016) (confirming that the patent specification "is the 'single best guide to the meaning of a disputed term,'" and holding that "construing the independent claim to exclude material covered by the dependent claim would be inconsistent" (quoting *Vitronics Corp.*, 90 F.3d at 1582)).

In explaining that a volume of 125 μL is filled in the device for it to emit 100 μL of the aqueous composition to the patient, the '253 patent references the "Pfeiffer/Aptar single-dose device." ('253 patent at 16:52–53). This device is mentioned as the preferred embodiment in the patent. ('253 patent at 16:19–20; 49:53–61). The Court "normally do[es] not interpret claim terms in a way that excludes embodiments disclosed in the specification," and the Court has seen no evidence indicating that this should be one of the rare instances where it should. *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276–77 (Fed. Cir. 2008). Thus, the Court finds that the claim term "a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 μL" requires no further construction, as "comprised" is a term of art that a person of ordinary skill in the art would understand, and the use of which is supported by the intrinsic evidence.

IV. CONCLUSION

For the aforementioned reasons, this Court declines to address Teva's indefiniteness challenge at this juncture and concludes that the claim term "a single reservoir comprising a pharmaceutical composition which is an aqueous solution of about 100 μL" requires no further construction. An appropriate Order accompanies this Opinion.

DATED: April 22, 2019

JOSE L. LINARES
Chief Judge, United States District Court